IFW AF/1642

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Shaughnessy	§	**ART UNIT:**
	§	**1642**
FILED: February 2, 2001	§	
	§	**EXAMINER:**
SERIAL NO.: 09/778,971	§	**Yaen, C.**
	§	
FOR: Evi27 Gene Sequence and Protein Encoded Thereby	§	
	§	**DOCKET:**
	§	**D6138**

Mail Stop Appeal Brief-Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313

ATTENTION: Board of Patent Appeals and Interferences

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8

Dear Sir:

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Respectfully submitted,

Date: April 23, 2004

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Shaughnessy	§	ART UNIT: 1642
	§	
FILED: February 2, 2001	§	EXAMINER:
	§	Yaen, Christopher
SERIAL NO.: 09/778,971	§	
	§	
FOR: Evi27 Gene Sequence And Protein Encoded Thereby	§	DOCKET: D6138
	§	

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APPELLANT'S BRIEF

This Brief is in furtherance of the Notice of Appeal filed in this case on March 8, 2004. The fees required under 37 C.F.R. §1.17(c) and any other required fees are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

In accordance with 37 C.F.R. §1.192(a), this Brief is submitted in triplicate.

INDEX OF SUBJECT MATTER

I. REAL PARTY IN INTEREST

The real party in interest is Board of Trustee of the University of Arkansas, the Assignee, as evidenced by an Assignment recorded in the Patent and Trademark Office at Reel 012022, Frame 0751 on July 20, 2001.

II. RELATED APPEALS AND INTERFERENCES

Appellant is aware of no other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF THE CLAIMS

Originally claims 1-21 were filed with this Application. Claims 9-21 were withdrawn. The pending claims 1, 5-8 are being appealed of which claims 1, 5 and 6 are an independent claim.

IV. STATUS OF AMENDMENTS

Subsequent to the Final Office Action mailed November 4, 2003, Applicants submitted a Response After Final which canceled claims 2-4 and amended claims 1 and 6. In an Advisory Action mailed February 25, 2004, the Examiner stated that the amendment will be entered upon appeal. The pending claims 1, 5-8 are shown in Appendix A.

V. SUMMARY OF THE INVENTION

The present invention describes the cloning and sequences of a novel IL-17 receptor-related gene in human and mouse whose expression is upregulated by viral integration in a murine acute myeloid leukemia. Gene transcription and protien expression were examined by northern blot analysis, western blot analysis and immunohistochemical staining. The gene disclosed herein may facilitate myeloid cell transformation and be involved in human disease (page 6, lines 3-10).

VI. ISSUES

35 U.S.C. §101

Whether claims 1-8 lack utility under 35 U.S.C. §101.

35 U.S.C. §112, First Paragraph

Whether claims 1-8 fail to comply with 35 U.S.C. §112, first paragraph, due to lack of utility.

VII. GROUPING OF CLAIMS

The rejected claims do stand or fall together.

VIII. ARGUMENTS

Rejection Under 35 U.S.C. §101

In the Final Office Action mailed November 4, 2003, the Examiner contends that the claims 1-8 lack specific and substantial utility, and the specification fails to support a utility for broad treatment of cancer and autoimmune diseases. This rejection is respectfully traversed.

Specific Utility

It is common and sensible for an applicant to identify several specific utilities for an invention, particularly where the invention is a product. However, regardless of the category of invention that is claimed, an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112; additional statements of utility, even if not credible, do not render the claimed invention lacking in utility (M.P.E.P. 2107.02).

In the present invention, in addition to a statement of possible utility in human disease, Applicant also asserts a role for the present invention (nucleic acid molecule of SEQ ID NO: 1) in regulating the development and growth of myeloid leukemia cells (page 66, lines 3-15). The present specification teaches that terminal differentiation of myelomonocytic precursor cells results in down regulation of Evi27 expression. However, proviral insertions at Evi27 result in constitutive expression of the Evi27 receptor. Binding of ligands to the Evi27 receptor triggers the release of TNF-α and IL-1β by the leukemic cells. The secreted TNF-α and IL-1β would in turn provoke production of multilinage hematopoietic growth factors, adhesion molecules, and

inflammatory cytokines by stromal cells. These stromal cell-derived factors then support the growth and survival of the leukemia cells. This model of leukemia cell growth is consistent with and supported by the fact that B160 leukemia cells are absolutely dependent on stromal feeder cell layer for growth and survival.

Thus, in view of the above disclosure, one of ordinary skill in the art would readily recognize that *Evi27*-encoded receptor mediates proinflammatory cytokine secretion and plays an important role in the growth of myeloid leukemia cells. Accordingly, one of ordinary skill in the art would reasonably conclude that modulating the expression of *Evi27*-encoded receptor can be exploited to regulate proinflammatory cytokine secretion and growth of myeloid leukemia cells. More specifically, inhibition of proinflammatory cytokine secretion and myeloid leukemia cell growth could be accomplished by inhibiting the expression and function of Evi27 receptor. It is well-known in the art that gene expression and/or function can be inhibited by anti-sense oligonucleotides or antibody.

In the instant case, one of ordinary skill in the art would readily recognize that Evi27 gene expression could be inhibited by anti-sense Evi27 oligonucleotides, and ligand binding to Evi27

receptor could be inhibited by antibody directed against the Evi27 receptor. A person having ordinary skill in this art would need to know the gene sequence of Evi27 receptor before anti-sense Evi27 oligonucleotides can be generated. A person having ordinary skill in this art would also needs to know the DNA sequence for the Evi27 receptor to construct recombinant Evi27 receptor protein for the generation of anti-Evi27 antibodies. The requisite DNA sequence for the Evi27 receptor is provided by the instant invention (SEQ ID NO: 1).

In view of the above remarks, Applicant submits that there is a specific utility for the instant invention (SEQ ID NO: 1) in regulating proinflammatory cytokine secretion and myeloid leukemia cell growth, and one of ordinary skill in the art could readily utilize the DNA sequence of the instant invention in standard conventional protocols to regulate myeloid leukemia cell growth *in vitro* or *in vivo*.

Substantial Utility

According to the M.P.E.P., a substantial utility is a real world use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a real world context of

use are not substantial utilities (M.P.E.P. 2107.01). Applicant submits that the above asserted utility for SEQ ID NO: 1 is a substantial use that does not require further research to identify a real world context of use. As discussed above, one of ordinary skill in the art would readily utilize SEQ ID NO: 1 to generate anti-sense Evi27 oligonucleotides or construct recombinant Evi27 receptor protein for the generation of anti-Evi27 antibodies. These oligonucleotides or antibodies can be readily employed in standard protocols to inhibit the expression and function of Evi27 receptor *in vitro* or *in vivo*, thereby inhibiting the growth of myeloid leukemia cells. Applicant submits that inhibiting the growth of myeloid leukemia cells *in vitro* or *in vivo* is a substantial use of the instant invention.

Credibility of Asserted Utility

An Applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101 (M.P.E.P. 2107.02). As discussed above, Applicant submits that the specification has provided a specific utility for the instant invention (SEQ ID NO: 1) in regulating proinflammatory cytokine secretion and myeloid leukemia cell growth. Applicant

further submits that one of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention disclosed and discussed above.

To overcome the presumption of truth that an assertion of utility by the applicant enjoys, Patent Office personnel must establish that it is more likely than not that one of ordinary skill in the art would doubt or question the truth of the statement of utility (M.P.E.P. 2107.02). Applicant submits that the Examiner has not addressed or raised any issue related to the model of regulating myeloid leukemia cell growth by Evi27 receptor protein as discussed above; nor does the Examiner provide any reason why one of ordinary skill in the art would have doubt on such model and question the truth of the statement of utility. Consequently, Applicant submits that the Examiner has failed to establish a *prima facie* case showing the claimed invention lacks utility.

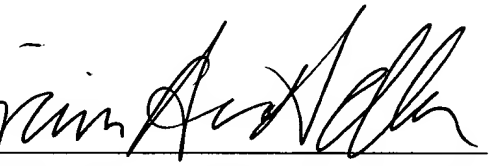
For the reasons given above, Applicant respectfully requests that the decision of the Examiner should be reversed, and that claims 1, 5-8 be allowed.

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1-8 stand rejected under 35 U.S.C. §112, first paragraph, due to lack of utility under 35 U.S.C. §101. As discussed above, Applicant submits that the instant specification has provided specific and substantial utility for the claimed invention that is credible to one of ordinary skill in the art. Accordingly, Applicant respectfully requests that the rejection of claims 1, 5-8 under 35 U.S.C. §112, first paragraph, be withdrawn.

Respectfully submitted,

Date: April 23, 2004



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CLAIMS ON APPEAL

1. An isolated nucleic acid molecule encoding an IL-17 receptor-related protein, said nucleic acid is selected from the group consisting of:

(a) an isolated nucleic acid molecule of SEQ. ID NO: 1; and

(b) an isolated nucleic acid molecule differing from the isolated nucleic acid molecules of (a) in codon sequence due to the degeneracy of the genetic code, and which encodes an IL-17 receptor-related protein.

5. An isolated genomic DNA encoding an IL-17 receptor-related protein, wherein said genomic DNA comprises coding sequences identical to nucleic acid molecule of claim 1.

6. A vector comprising a nucleic acid molecule of SEQ. ID NO: 1 and regulatory elements necessary for expressing said nucleic acid molecule in a cell.

7. A recombinant host cell comprising with the vector of claim 6, wherein said vector expresses an IL-17 receptor-related protein.

8. The host cell of claim 7, wherein said cell is selected from group consisting of bacterial cells, mammalian cells, plant cells and insect cells.